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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,124	02/21/2002	Vivien Chan	PP-016336.002	8573

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Chiron Corporation  
Intellectual Property - R440  
P.O. Box 8097  
Emeryville, CA 94662

EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/09/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/081,124

Applicant(s)

CHAN ET AL.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a method for detecting a cancerous colon cell, classified in class 435, subclass 6. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie election is also required.
- II. Claims 6-8, drawn to a method for assessing the cancerous phenotype of a colon cell, classified in class 436, subclass 64. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie election is also required.
- III. Claims 9-12 and 23, drawn to a method for suppressing or inhibiting a cancerous phenotype of a cancerous cell, classified in class 436, subclass 64. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie election is also required.
- IV. Claim 13, drawn to a method for assessing the tumor burden of a subject, classified in class 436, subclass 64. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie election is also required.
- V. Claims 14-18, drawn to a method for identifying a gene product as a target for a cancer therapeutic, classified in class 436, subclass 64. If this Group is elected then the below

summarized sequence election is also required. Also, if this Group is elected then TWO of the below summarized specie elections are also required.

- VI. Claims 19-22, drawn to a method for identifying agents that decrease biological activity of a gene product, classified in class 435, subclass 7.1. If this Group is elected then the below summarized sequence election is also required. Also, if this Group is elected then ONE of the below summarized specie election is also required.

#### **Sequence Election Requirement for Groups I-VI:**

The claims in this invention read on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences. For amino acid/polypeptide or nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR

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1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

### **Specie Election Requirement for Groups I-VI:**

This application contains claims directed to the following patentably distinct species of the claimed invention:

For Groups I and IV-VI:

Specie A: a gene product which is a nucleic acid

Specie B: a gene product which is a polypeptide

For Groups II, III, and V:

These Groups are directed to multiple species, namely cancerous phenotypes. If any of these Groups are elected, it is requested that Applicants elect a specific cancerous phenotype (i.e. metastasis, aberrant cellular proliferation relative to a normal cell, loss of contact inhibition of cell growth, etc.) so that examination on the merits of this application may begin.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for each applicable specie election requirement for the prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The distinctness of different types of cancerous phenotypes (Groups II, III, and V) is because these phenotypes contain a unique set of characteristics not necessarily present in the other phenotypes. This distinctness or

independence of a nucleic acid versus a polypeptide (Groups I and IV-VI) is because these species are directed to different chemical types regarding the critical limitations, including structure and function. The completely separate chemical and entity types of the invention species are often separately characterized and published in literature, thus adding to the search burden if all species were examined together. Also, processing that may connect two species does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, these species are independent and/or distinct invention types for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should an applicant traverse the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different processes, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-VI are directed to methods that recite structurally and functionally distinct elements, are not required one for the other, and/or achieve different goals. Group I requires detection a cancerous status of a colon cell via probe usage which are not required by any other group. Group II requires assessment of the cancerous phenotype of a colon cell which is different from the goals of the other groups. Group III is directed to the suppression or inhibition of a cancerous phenotype via antisense polynucleotide introduction which differs from the goals of the other groups. Group IV requires assessing the tumor burden of a subject via determination of whether gene product expression detection levels are met without the use of controls which differs from other groups. Group V seeks to identify gene product targets which is different from the goals of the other groups. Group VI identifies agents that decrease biological activity of a gene product with reference to controls which differs from goals of the other groups. These distinct methods are often separately characterized and published in literature and would add undue search burden if they were all examined together. Thus, they are considered distinct invention types for restriction purposes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 7, 2003

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER